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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,400	06/27/2003	Michael J. Pugia	MSA-3453	7945

7590 01/10/2006

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EXAMINER	
SINES, BRIAN J	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,400	PUGIA ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

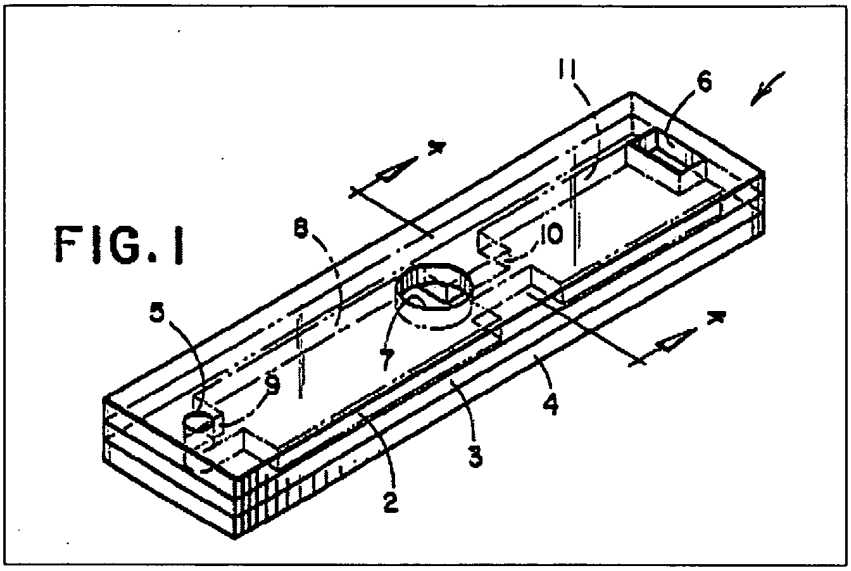
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

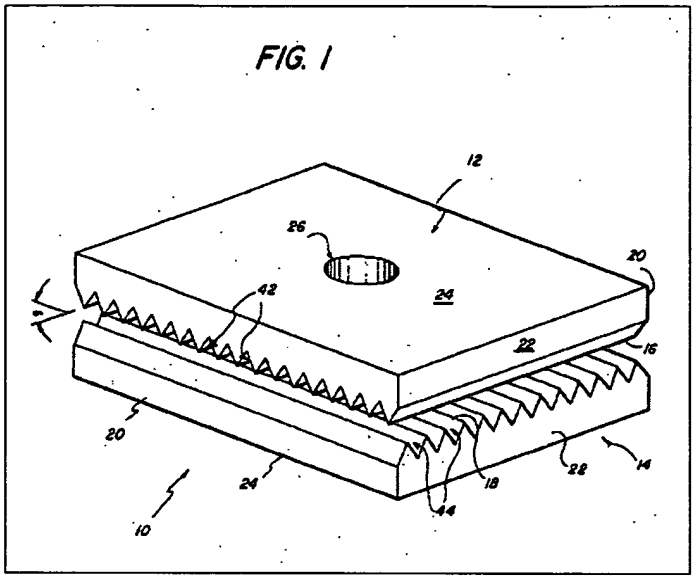
1. Claims 1, 5 – 9 and 13 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blatt et al. (U.S. Pat. No. 4,761,381) (hereinafter "Blatt") in view of Columbus (U.S. Pat. No. 4,233,029).

Regarding claims 1, 8 and 9, Blatt teaches an apparatus comprising: a well (e.g., sample chamber 8 with reagent layer 4) with a surface immobilized reagent; an entry port (7); a capillary passageway (channel 10); and a vent (e.g., air relief port 5) (see col. 5, lines 1 – 55; figure 1). Blatt teaches that the disclosed apparatus can accommodate sample volumes of 5 – 10 microliters (see col. 4, lines 24 – 34).



Blatt does not specifically teach the incorporation of a microstructure for directing sample flow in a predetermined uniform manner through the apparatus.

Columbus teaches an analytical apparatus (10) comprising: at least one space (e.g., the space between interior surfaces 16 & 18) for containing a test sample and a reagent on a substrate (e.g., the bottom surface 18); a microstructure (grooves 42 & 44) disposed in the space for directing the test sample over the substrate in a uniform manner. As fluid is introduced into the space via port 26, the introduced fluid would displace and thereby purge any air contained within this space during use (see col. 3, line 16 – col. 4, line 68; figure 1).



Hence , as evidenced by Columbus, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of such microstructures within an analytical microfluidic apparatus for the intended purpose of facilitating effective sample introduction and uniform distribution (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating these microstructures with an analytical microfluidic apparatus as disclosed by Blatt. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate these disclosed microstructures onto the substrate surface of the Blatt apparatus in order to facilitate effective sample introduction and subsequent analysis.

Regarding claim 5, Columbus teaches that the microstructure (e.g., groove 42) is also positioned above the substrate (e.g., substrate surface 18) (see figure 1).

Regarding claim 6, Columbus teaches that the microstructure (e.g., groove 44) can also be in contact and further integrated within the substrate (e.g., substrate surface 18) (see figure 1).

Regarding claim 7, Columbus also teaches the incorporation of a microstructure (truncated ridges 46) comprising a ramp or slanted or inclined portion and a substrate plateau (e.g., the flat top surface of the truncated ridge 46) (see col. 8, lines 1 – 67; figure 7a).

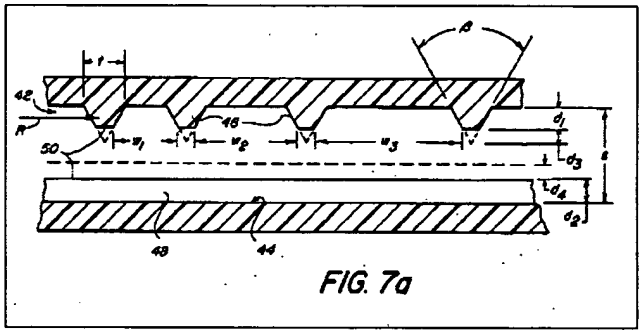


FIG. 7a

Regarding claims 9 and 13 – 16, as discussed above, Blatt in view of Columbus teaches all of the apparatus structure recited in the claimed method, which merely recites the conventional operation of that apparatus structure. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the methodology recited in the instant claims upon the apparatus of Columbus, as such is the intended operation of that apparatus.

2. Claims 2 – 4, 10 – 12 and 27 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blatt in view of Columbus, as applied to the claims above, and further in view of Peters (U.S. Pat. No. 6,296,126 B1) (hereinafter "Peters").

Regarding claims 2 and 27, neither Blatt nor Columbus teaches the incorporation of microstructures comprising post or column structures diposed at a right angle to the flow of the test sample. Peters does teach the use of post or column structures (9, 10 & 22) within an

analytical microfluidic apparatus for facilitating effective fluid flow within the apparatus (see col. 3, line 30 – col. 39; figures 3b & 7a).

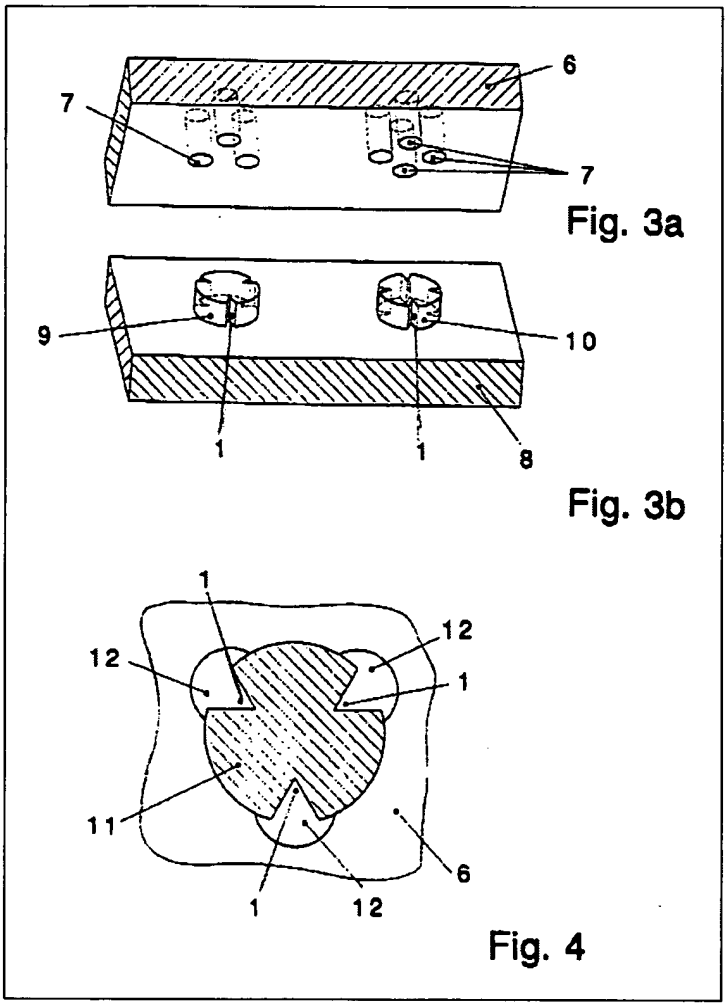
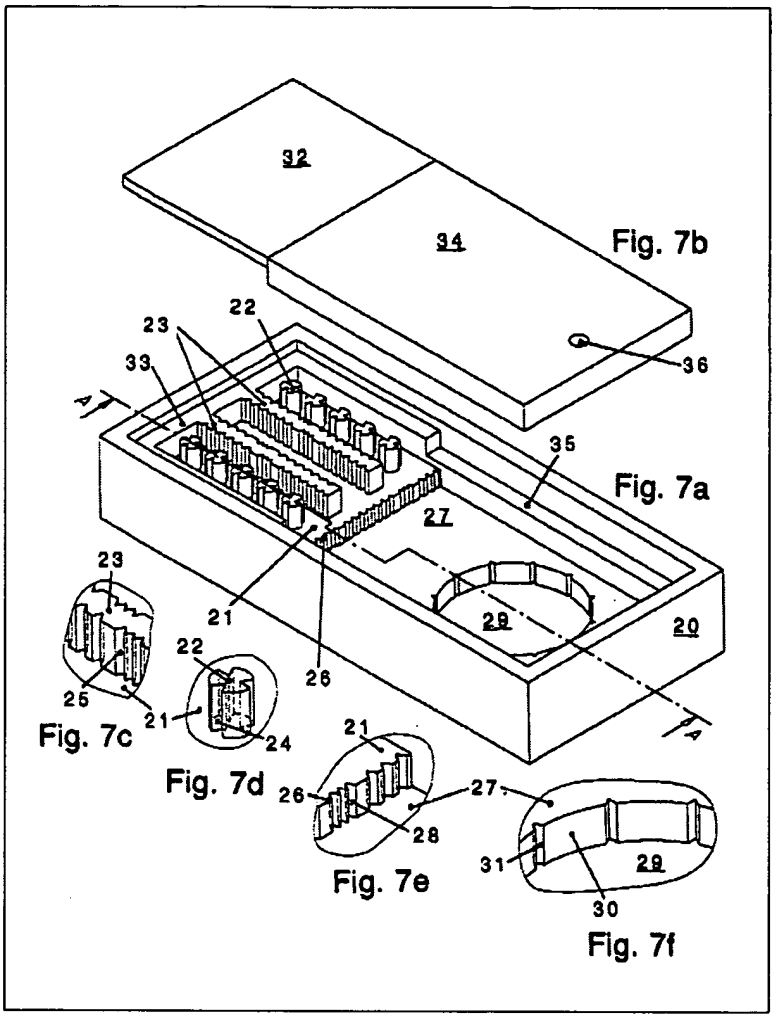


Fig. 3a

Fig. 3b

Fig. 4



Hence, as evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of these post or column structures within an analytical microfluidic apparatus for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these post structures within a microfluidic apparatus for facilitating effective fluid control. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ

375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of an array of post structures comprising one or more than one column of posts disposed at a right angle to the flow of fluid within disclosed the analytical microfluidic apparatus.

Regarding claim 3, as illustrated in figure 7a, Peters indicate that multiple columns of posts (22 & 23) may be incorporated into the apparatus. In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a second column of posts, as indicated by Peters, within the disclosed apparatus in order to facilitate effective fluid flow control.

Regarding claim 4, Peters does teach the incorporation of wedge-shaped cut-out structures (columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4). Consequently, a person of ordinary skill in the art would have recognized the suitability of incorporating such wedge-shaped cut-out post structures within an analytical microfluidic device for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate post structures comprising at least one wedge-shaped cut-out as recited in claim 4, to provide for effective fluid flow control.

Regarding claims 10 – 12 and 27 – 32, as discussed above, Blatt in view of Columbus and Peters teaches all of the apparatus structure recited provided for in the claimed method,

which merely recites the conventional operation of that apparatus structure. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the methodology recited in the instant claims upon the disclosed apparatus, as such is the intended operation of that apparatus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).